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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,127	12/09/2005	Ralf Ragnar	I33087.09101(101077-1PUS)	2806
52286	7590	09/25/2007	EXAMINER	
Pepper Hamilton LLP			VALENROD, YEVGENY	
500 Grant Street			ART UNIT	PAPER NUMBER
One Mellon Bank Center, 50th Floor			1621	
Pittsburgh, PA 15219-2502			MAIL DATE	DELIVERY MODE
			09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/560,127

Applicant(s)

RAGNAR ET AL.

Examiner

Yevgeny Valenrod

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/22/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Rejection of claim 8 under 35 USC 112 1<sup>st</sup> paragraph is withdrawn in view of applicants' amendment.

Applicants remarks filed on 7/13/07 have been considered and are not found persuasive.

Rejection of claim 10 under 35 USC 112 1<sup>st</sup> paragraph is maintained.

Rejection of claims 1-8 and 10-12 under 35 USC 103 is maintained. New claim 13 is included in the rejection.

New claim 13 is rejected under 35 USC 112 2<sup>nd</sup> paragraph.

### ***Reply to applicants' remarks***

Rejection of claim 10 under 35 USC 112 1<sup>st</sup> paragraph.

Applicant has traversed the rejection of claim 10 under 112 1<sup>st</sup> paragraph, arguing that the said claim is enabled for prevention of type 2 diabetes. In support of the argument applicant has provided evidence (Diabetes Care 25,(4): 742-749 (2002)) alleging that the statement on pages 743-744 provides enablement for prevention of type 2 diabetes.

Applicant has also provided a definition of prevention according to Merriam Webster Dictionary: to keep from happening.

Examiner disagrees with applicants' interpretation of the statement of pages 743-744 of the Diabetes Care reference. The said statement recites: "In summary, our

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knowledge of the early stages of hyperglycemia that portend the diagnosis of diabetes and the recent success of major intervention trials clearly show that individuals at high risk can be identified and diabetes delayed if not prevented." The statement does not support the claim that diabetes can be prevented in 100% of the patients. In fact the evidence on which the statement is based recites: "after 3.2 years there was a 58% percent reduction in occurrence of diabetes" (p 742, column 3, line 11-13) and in another study " After average follow-up of 2.8 years, a 58% relative reduction in the progression to diabetes" (p742, column 3 paragraph 2, lines 18-21). 1) Neither study suggests a 100% preventive therapy. 2) The studies are limited to 3.2 years and 2.8 years time limit and demonstrate reduction of progression to diabetes not prevention of diabetes. The studies offer no information on if any of the 58% of patients in which reduction in progression to diabetes was observed, were diagnosed with diabetes after the 3.2 or 2.8 years of study were over.

If one is to define prevention as: to keep from happening. The evidence provided by the applicant fail to meet that limitation. The article in Diabetes Care at best demonstrates that the onset of diabetes can be delayed in 58% of cases.

Rejection of claims 1-8 and 10-13 under 35 USC 103.

Applicant has traversed the rejection of claims 1-8 and 10-12 under 35 USC 103 on the basis that the Examiner failed to provide motivation for one ordinary skill in the art to select Magnesium or Calcium salts of the free acid taught by Linstedt et al.

Applicants' argues:

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1) "The mere fact that prior art genus contains a small number of members does not create a *per se* rule of obviousness" (remarks page 6, 4<sup>th</sup> paragraph, lines 3-4).

2) "... Linstedt et al. do not teach method of preparation for any crystalline forms of the compound..."

Applicants' arguments are not found persuasive.

1) It is true, Linstedt et al do not teach preparation of crystalline form. However a method preparation of crystalline form of the title compound is not claimed in the instant application. Linstedt et al. describe a crystalline form in the abstract (see abstract, line 2).

2) Choosing a counter ion from a finite number of predictable solutions is obvious. In view of the teaching of Linstedt et al. that alkaline earth metal salts are preferred counter ions for the compound of formula I, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If doing so leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. Magnesium and Calcium are well known pharmaceutically acceptable counterions. Applicant has failed to provide evidence indicating that using Magnesium or Calcium salt of the compound of formula 1 results in unexpected results. Examiner maintains that absent such evidence the invention is obvious.

Claim 13 is included in the 35 USC 103 rejection already of record.

***New rejection under 35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the limitation " hypertension, hyperlipidemia, dyslepidemia diabetes or obesity " in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 13 depends on claim 11 where the disorder is limited to atherosclerosis.

***Conclusion***

Claims 1-8 and 10-13 are pending

Claims 1-8 and 10-13 are rejected

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

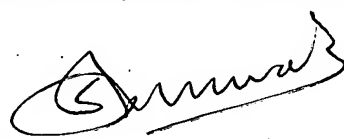
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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